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## MEMORANDUM

## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: March 15, 1999

FROM: Complex Drug Substances Coordinating Committee

/Conjugated Estrogens Working Group 1/1/1/ 40

THROUGH: Director, Center for Drug Evaluation and Research

TO: Director, Division of Reproductive and Urologic Drug

Products (HFD-580)

SUBJECT: Addendum to January 6, 1999, Conjugated Estrogens

Nomenclature Memorandum

This memorandum amends decisions in a Center memorandum entitled Conjugated Estrogens nomenclature and dated January 6, 1999.

I. Nomenclature for Natural Conjugated Estrogens

The January 6, 1999, memorandum suggested that Premarin might be renamed as Natural Conjugated Estrogens A. CDER does not intend to implement this approach and will retain the current USP name. This decision may need to be revisited if a second natural conjugated estrogens is approved.

II. Use of a comma between "Conjugated Estrogens" and the letter modifier.

After finalization of the January 6, 1999, memo, CDER review staff recognized that a comma should have appeared between "Conjugated Estrogens" and the letter modifier. This approach is based on the intent to have one USP monograph with the title "Synthetic Conjugated Estrogens." This monograph will describe different mixtures of synthetic

conjugated estrogens which will be identified with a letter modifier. If the name were to appear without a comma, USP might develop separate monographs for each of the different mixtures.